

REMARKS:

In response to the Office Action mailed January 8, 2008, claims 1, 40, 92, and 149 have been amended, and new claims 181-200 have been added. Therefore, claims 1, 40, 92, 95-99, 101, 105-110, 113, 114, 149-152, 154-158, and 181-200 are currently pending in the application with claims withdrawn as directed to nonelected species.

The current claim amendments and new claims are fully supported by the original disclosure as filed, and do not present new matter. See, e.g., paragraphs [0061], [0111]-[0118], [0127], [0156], and [0160], and in FIGS. 12-15. No new matter has been introduced.

In the Office Action, claims 1, 40, 92, 95, 96, 98, 99, and 101 were rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 6,773,390 (“the McDaniel reference”), claims 92, 97, 149-152, 154, 157, and 158 were rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 6,371,904 (“the Sirimanne et al. reference”), and claims 149-152 and 155-158 were rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 7,182,725 (“the Bonan et al. reference”). In addition, claims 105 and 106 were rejected under 35 U.S.C. § 103(a) as unpatentable over the McDaniel reference, claims 107-110 and 113 were rejected under 35 U.S.C. § 103(a) as unpatentable over the Sirimanne reference in view of U.S. Patent No. 4,427,005 (“the Tener reference”), and claim 114 was rejected under 35 U.S.C. § 103(a) as unpatentable over the Sirimanne reference in view of the Tener reference and further in view of the McDaniel reference. Because none of the cited references, either alone or in combination, discloses, teaches, or suggests the subject matter of the present claims, the rejections should be withdrawn.

Turning first to the McDaniel reference, a radioactive source ribbon assembly 100 is

disclosed that includes an inner assembly including a radioactive source 104, a core 106, a radioactive resistant sleeve 108 that encases the radioactive source 104 and core 106, and an outer jacket 102. Col. 3, lines 62-67. The assembly 100 also includes distal and proximal seals 114, 116 for sealing the inner assembly within the outer jacket 102. Col. 4, lines 2-5.

Turning to the present claims, claim 1 recites an implantable brachytherapy treatment system that includes a therapy delivery portion comprising at least one flexible non-dissolving casing and a support member or shielding enclosed within the casing and extending between proximal and distal ends of the casing; and one or more radiation sources removably received in the casing.

First, the McDaniel reference does not disclose, teach, or suggest a support member extending between proximal and distal ends of a casing. Even if the McDaniel core 106 could constitute a support member (which Applicants do not concede), the core 106 does not extend between proximal and distal ends of the outer jacket 102, but only extends partially from the proximal end of the outer jacket 102.

Second, the McDaniel reference fails to disclose, teach, or suggest one or more radiation sources *removably* received in a casing, as claimed. Instead, the McDaniel radioactive source 104 is sealed within the outer jacket 102, and therefore cannot be removed from the outer jacket 102.

Accordingly, claim 1 is neither anticipated by the McDaniel reference. Further, the McDaniel assembly is not intended for introduction through tissue, e.g., into a target tissue region of a breast. Instead, the McDaniel assembly is intended for delivery into a blood vessel to prevent restenosis after angioplasty. See, McDaniel, col. 1, line 13-col. 2, line 5. Thus, the

McDaniel assembly would not be implanted within a patient's body for an extended period of time, but would merely be introduced after angioplasty, and then immediately removed.

Accordingly, because the McDaniel assembly is intended for an entirely different purpose, claim 1 would also not be obvious over the McDaniel reference.

Turning to claim 40, a kit is recited for delivering brachytherapy to a target tissue region of a body that includes a removably implantable elongate brachytherapy device comprising a therapy delivery portion; and one or more low dose radiation (LDR) radioactive sources secured to the therapy delivery portion; at least one non-dissolving flexible tail portion; and a catheter comprising a proximal end, a distal end, a lumen extending therebetween sized for receiving the brachytherapy device for delivering the brachytherapy device to the target tissue region, and a support member extending adjacent the lumen between the proximal and distal ends.

As explained above, the McDaniel reference fails to disclose, teach, or suggest a catheter including a support member adjacent a lumen between proximal and distal ends thereof, nor a lumen for receiving a brachytherapy device, as claimed. Therefore, claim 40 is also neither anticipated by nor otherwise obvious over the McDaniel reference.

For similar reasons, claim 92 is also neither anticipated by nor otherwise obvious over the McDaniel reference. Claim 92 recites one or more radiation sources *removably* disposed within a lumen of a tubular member for delivering radiation therapy to the target tissue region along a second non-linear axis, and a support member extending between proximal and distal ends of the tubular member such that the support member is adjacent the one or more radiation sources when the one or more radiation sources are disposed within the lumen.

In addition, with respect to claim 105, the McDaniel reference does not disclose, teach, or

suggest a plurality of additional elongate tubular members configured to be implanted along a non-linear axis within a target tissue region. Because the McDaniel assembly is intended to be delivered into a blood vessel after angioplasty, there would be no way to implant a plurality of tubular members through such a blood vessel. Angioplasty is intended to be a nonsurgical procedure, while brachytherapy within a breast is a surgical procedure, as described throughout the present application. For this additional reason, claim 105 is not obvious over the McDaniel reference.

Finally, for similar reasons, new claims 181-200 are also neither anticipated by nor otherwise obvious over the McDaniel reference. For example, the McDaniel reference does not teach or suggest an implantable brachytherapy treatment system for treating a target tissue region within a breast, as recited in claims 181 and 191. In particular, claim 181 recites a support member extending between proximal and distal ends of a tubular member *outside* first lumen, the support member configured for delivering the tubular member through tissue in a straight configuration and deploying the tubular member in a curved configuration within or around the target tissue region; and a radiation source receivable in the first lumen of the tubular member for delivering radiation therapy to the target tissue region in the curved configuration. Instead, the McDaniel core 106 is disposed within the same lumen as the radioactive source 104, and not outside the lumen. Further, the McDaniel reference does not disclose a support member or strip of material *extending between proximal and distal ends* of a tubular member or a radiation source *receivable* in a first lumen of a tubular member, as claimed.

Turning to the Sirimanne et al. reference discloses subcutaneous cavity marking devices, and fails to teach or suggest anything about brachytherapy. In particular, with reference to FIGS.

5A-5E, the Sirimanne et al. reference discloses radiopaque or echogenic wires that may be deployed into a tissue cavity. Col. 13, lines 54-57. The wire markers are not tubular members and do not receive radiation sources. Although the wires may be “radiopaque,” this does not mean that the wires are radiation sources. Instead, “radiopaque” merely means “opaque to radiation; visible in x-ray photographs and under fluoroscopy.” See dictionary.com. For this reason alone, none of the present claims are anticipated by or otherwise obvious over the Sirimanne et al. reference.

With respect to the Bonan et al. reference, a catheter 20 is disclosed that is intended to be inserted through a patient’s vascular system into the patient’s heart to ablate tissue at the AV node or other site. Col. 6, lines 38-44. With reference to FIGS. 9a and 9b, the Bonan et al. reference discloses that the catheter 62 may include steering wires, but fails to teach or suggest anything about support members.

Turning to claim 149, a system is recited for delivering radiation therapy to a target tissue region within a breast that includes at least one therapy delivery element comprising a tubular member, the tubular member comprising a support member extending between proximal and distal ends thereof constructed to cause bending in a predetermined, preferred plane of bending to provide conformance of the at least one therapy delivery element to the target region of the lumpectomy cavity to be irradiated; and one or more radiation sources removably carried by the tubular member.

The Bonan et al. reference does not disclose, teach, or suggest tubular member comprising a support member extending between proximal and distal ends thereof constructed to cause bending in a predetermined, preferred plane of bending, as claimed. Accordingly, claim

149 and its dependent claims are neither anticipated by nor otherwise obvious over the Bonan et al. reference.

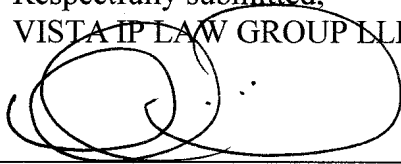
For similar reasons to those given above, new claims 181-200 are also neither anticipated by nor otherwise obvious over the Bonan et al. reference.

Finally, the Tener reference fails to provide any additional teaching or suggestion of the features wholly absent from the other cited references. Instead, the Tener reference merely discloses a template for guiding needles into a patient's breast. Therefore, even the Tener reference could be properly combined with the other cited references (which Applicants do not concede given the entirely different applications of the other cited references), the present claims are not obvious over the cited references.

Applicants respectfully submit that the application is in condition for allowance in view of the forgoing amendments and remarks. Accordingly, reconsideration and allowance of the application is requested.

If there are any remaining issues that can be resolved by telephone, Applicants invite the Examiner to contact the undersigned at the number indicated below.

Respectfully submitted,
VISTA IP LAW GROUP LLP



By _____

William A. English
Reg. No. 42,515
Attorneys for Applicants

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2040 Main Street, 9th Floor
Irvine, CA 92614
Telephone: (562) 665-3953
Facsimile: (949) 625-8955